Suggested Format for Residue Chemistry Study Reports

Water, Fish, and Irrigated Crops

OPPTS 860.1400

The purpose of this document is to suggest the format for final reports (right column) and to provide instructions for creation of Adobe PDF electronic submission documents (left column). The format is modeled after the NAFTA Data Evaluation Record template that will be used by OPP's and PMRA's scientists when this type of study is reviewed. The format is in outline form. The study report will include text and standard tables (detailed below).

Regarding PDF, both 'bookmarks' and 'links' are referenced. Bookmarks and links are similar in function in that both provide the reader with a way to move efficiently through a document as well as across documents. Bookmarks are a type of link that appear in the navigation pane on the left side of the PDF Reader user screen. Links appear within the body of a document as blue text. They permit the reader to jump to other locations with related information in the same document or other electronic documents.

Residue Chemistry Study Reports – WATER, FISH & IRRIGATED CROPS	
Instructions to create PDF	**Document Format**
Create Bookmarks for each item in Document Format column.	• Study Title Page. - Statement of Data Confidentiality. *No confidentiality claims can be made for electronically submitted studies at this time.* • GLP Statement. • QA Statement. • Table of Contents.
Create links in summary to related text and tables in body of study report or appendices.	• Executive Summary. - Summary of Background Information & Experimental Design. - Summary of Results.
Create links to related tables.	• Background Information and Experimental Design. - Test Compound – See Tables 1 and 2. - Experimental Design – See Tables 3 - 7. - Analytical Methodology. - Study Site Information – See Tables 8 - 10. • Results and Discussion – See Tables 11 - 21

Table Formats

Tables should be imported into the PDF document from their native formats. See OPP's detailed technical specifications for creating PDF for details.

Table 1: Test Compound Nomenclature.

Compound	Chemical structure
Common name	
Company experimental name	
IUPAC name	
CAS name	
CAS #	
End-use product/EP	

Table 2: Physicochemical Properties.

Parameter	Value	Reference
Melting point/Range		
pH		
Density		
Water solubility (__°C)		
Solvent solubility (mg/L at __°C)		
Vapor pressure at __°C		
Dissociation constant (pK_a)		
Octanol/water partition coefficient Log (K_{ow})		
UV/visible absorption spectrum		

Table 3: General Test Organism Information.

Species	Breed	Age	Gender	Weight at study initiation (kg)	Health status	Description of housing/holding area

Table 4: Test Organism Dietary Regime.

Diet	Acclimation period	Predosing

Table 5: Test Organism Dosing Regime.

Regime (oral, dermal, aquaculture)	Level of administered dose (mg/day)	Food consumption (kg/day)	Vehicle (capsule, feed, bolus, etc.)	Timing/ Duration

Table 6: Test Material Characteristics.

Chemical structure	[Insert Structure]	[Insert Structure]
Radiolabel position		
Lot number		
Purity		
Specific activity (Bq)		
Code		

Table 7: Sample Collection Information.

Roe	Interval from last dose to sacrifice	Tissues harvested & analyzed
XXX daily	XXX hours	

Table 8: Soil Characterization.

Study Location (City, State)	Year	Soil characteristics			
		Type	%OM	pH	CEC

Table 9: Commodity, Application, and Harvesting Information.

Location (City, State)	Year	EP[1]	Application						Tank mix adju-vants
			Tim-ing	Rate, lb a.i./A (kg a.i./ha)	RTI[2] (days)	Treat. No.	Method	Total rate, lb a.i./A (kg a.i./ha)	

[1]EP = End-use Product
[2]RTI = Retreatment Interval

Table 10: Trial Numbers and Geographical Locations.

NAFTA Growing Region	Crop 1				Crop 2				Crop n			
	Canada		US		Canada		US		Canada		US	
	Sub	Req	Sub	Req	Sub	Req	Sub	Req	Sub	Req	Sub	Req
1												
1A												
2												
⋮												
21												
Total												

Sub = submitted, Req = requested

Table 11: Summary of Concurrent Recoveries of [*chemical*] from [*matrix*].

Matrix	Analyte	Spike level (mg/kg)	Recoveries (%)	Mean ± std. dev.

Table 12: Summary of Storage Conditions.

Matrix (RAC or Extract)	Storage temp. (°C)	Actual storage duration (days or months)	Limit of demonstrated storage stability (days or months)

Table 13: Identification, Characterization, and Distribution of Residues.

Matrix	Aa-label		Bb-label	
	% TRR	ppm	% TRR	ppm
Total recovery				

Table 14: Quantitative Distribution of the Parent and the Metabolites in Fish when Dosed with ^{14}C–labeled Test Compound X [Note: Add rows to the table as needed to accommodate the fractionation/characterization scheme. Create additional tables as needed to accommodate additional radiolabel positions.]

Metabolite Fraction	Matrix 1 (TRR = xx ppm)		Matrix 2 (TRR = xx ppm)		Matrix N (TRR = xx ppm)	
	% TRR	ppm	% TRR	ppm	% TRR	ppm
Surface wash						
[Add a row for each identified compound]						
[Unidentified compound]						
Organosoluble						
[Add row for each identified compound]						
[Unidentified compound]						
Aqueous soluble						
[Add row for each identified compound]						
[Unidentified compound]						
Total extractable (Aqueous + organic)						
Total identified						
Total unidentified						
Total bound residues (PES)						
% Accountability Total (ppm)/TRR (ppm)* 100						

Table 15: Summary of Characterization and Identification of Radioactive Residues in Fish Matrices Following Application of Radiolabeled [*chemical*] at [*rate*] [Note: Create additional tables as needed to accommodate additional radiolabel positions.]

Compound	Muscle		Fat		Kidney		Liver		Milk/Eggs	
	% TRR	ppm	% TRR	ppm	% TRR	ppm	% TRR	ppm	% TRR	ppm
[Parent]										
[Metabolite 1]										
[Metabolite 2]										
[Metabolite 3]										
[Metabolite 4]										
Total identified										
Total characterized										
Total extractable										
Total bound										

Table 16: Identification of Compounds from Metabolism Study.

Common name/code	Chemical name	Chemical structure

Table 17: Residue Data from [*type of study (irrigated crops, fish, water)*] in [*commodity*] with [*chemical*]

Location (City, State)	Year	Commodity variety	Matrix	Formulation	Total rate lb a.i./A (kg a.i./ha)	PHI (days)	Residues (ppm)

Table 18: Summary of Residue Data from [*type of study (irrigated crops, fish, etc.)*] with [*chemical*].

Commodity/ Matrix	Total application rate lb a.i./A (kg a.i./ha)	PHI (days)	Residue levels (ppm)					
			n	Min	Max	HAFT*	Mean	Std. dev.

*Highest Average Field Trial

Table 19: Water Characterization.

Study site	Type	Hardness /Salinity	pH	Turbidity	

Table 20: Maintenance Chemical Information.

Study site	Pesticide or Fertilizer applied	Rate	Date

Table 21: Temperature Data.

Study site	Study period	Actual average minimum (C°)	Historic average minimum (C°)	Actual average maximum (C°)	Historic average maximum (C°)

Table 22: Rainfall Data.

Study site	Study period	Actual rainfall average (cm)	Historic rainfall average (cm)